



Food and Drug Administration  
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March 11, 2015

Ivera Medical Corporation  
Mr. Don Canal  
Vice President RA/QA  
3525 Del Mar Heights Road Suite 430  
SAN DIEGO, CA 92130

Re: K140657

Trade/Device Name: Curos Red Port Protector  
Regulation Number: Unclassified  
Regulation Name: Pad, Alcohol, Device Disinfectant  
Regulatory Class: Unclassified  
Product Code: LKB  
Dated: November 5, 2015  
Received: November 6, 2015

Dear Mr. Canal:

This letter corrects our substantially equivalent letter of December 4, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina  
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

## Indications for Use

510(k) Number (if known)  
K140657

Device Name  
Curos Red Port Protector

### Indications for Use (Describe)

The Curos Red is intended for use on dialysis catheter female Luers and open female ports on stopcocks as a disinfecting cleaner prior to line connection and to act as a cover between line accesses. In three (3) minutes after application, the Curos Red will disinfect the female Luer and act as a cover until removed. The effectiveness of the Ivera Curos Red was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curos Red may be used in the home or healthcare facility.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## **510(k) Summary** K140657

### **General Company Information**

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**Date Prepared: November 4, 2014**

### **General Device Description**

The Curos Red Port Protector contains 70% Isopropyl alcohol and is intended for use on dialysis catheter open female luers and open female ports on stopcocks as a disinfecting cleaner prior to line connection and to act as a cover between line accesses. The Curos Red has a highly visible red color that may allow improved compliance monitoring by easy visual verification to ensure that all open female luers are disinfected and covered. The Curos Red may be used in the home or healthcare facility.

Common Name: **Pad, Alcohol**  
Trade Name: **Curos Red Port Protector**  
Classification: Unclassified Device, product Code LKB

### **Predicate Devices**

K111992 Curos Port Protector, Ivera Medical, Inc.  
K101385 Dual Luer Lock Cap, Baxter Healthcare Corporation

### **Intended Use (Indications)**

The Curos Red is intended for use on dialysis catheter female luers and open female ports on stopcocks as a disinfecting cleaner prior to line connection and to act as a cover between line accesses. In three (3) minutes after application,

the Curo Red will disinfect the female luer and act as a cover until removed. The effectiveness of the Ivera Curo Red was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curo Red may be used in the home or healthcare facility.

**Comparison with Predicate Device**

**Subject Device to Predicate Technological Comparison Table**

Characteristic	Subject Device	Curo Port Protector K111992	Predicate Device
Device name	Curo Red Port Protector	Curo Port Protector	Dual Luer Lock Cap
Common Name	Alcohol, disinfecting pad	Alcohol, disinfecting pad	IV Administration set
Manufacturer	Ivera Medical	Ivera Medical	Baxter Healthcare Company
510(k) number	Subject Device	K111992	K101385
Regulation number, product code	Unclassified, Preamendment device, product code: LKB	Unclassified, Preamendment device, product code: LKB	IV Administration Set, 21 CFR 880.5440, FPA, Class II
Indications for use	The Curo Red is intended for use on dialysis catheter female Luers and open female ports on stopcocks as a disinfecting cleaner prior to line connection and to act as a cover between line accesses. In three (3) minutes after application, the Curo Red will disinfect the female Luer and act as a cover until removed. The effectiveness of the Curo Red was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curo Red may be used in the home or healthcare facility.	The Curo is intended for use on swab-able luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. Curo™ will disinfect the valve three (3) minutes after application and act as a physical barrier to contamination for up to seven (7) days (168 hours) if not removed. The effectiveness of Curo Protectors were tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli and Pseudomonas aeruginosa, Candida glabrata, Candida albicans and was found to have >4 log reduction. The Curo Port Protector may be used in the home or healthcare facility.	The Dual Luer Lock Cap is indicated for use as a cap for male or female ports on medical devices such as manifolds, stopcocks or sets.
Disinfectant – active ingredient	70% Isopropyl Alcohol	70% Isopropyl Alcohol	None

Characteristic	Subject Device	Curoos Port Protector K111992	Predicate Device
Male Luer Connection	No	No	Yes
Connection to open female luer connection	Yes	No	Yes
Connection to needleless IV Valve	Yes	No	No
Length	0.47 inches	0.40 inches	0.365
Diameter	0.50 inches	0.54 inches	0.205
User Population	Home and hospital use	Home and hospital use	Home and hospital use
Colorants Used (type, amount, concentration)	Red, molded plastic, 3% concentration	Translucent green, molded plastic, 3% concentration	White Plastic. Exact material formulation and colorant is not available
Provided Sterile	Yes	Yes	Yes
Single Use Device	Yes	Yes	Yes
Plastic Housing to remain in place	Yes	Yes	Yes

### **Substantial Equivalence Performance Testing**

Ivera Medical has provided non-clinical performance test data that demonstrates the pre-defined acceptance criteria for a disinfecting device has been met. This acceptance criteria is defined as a bacteria count reduction of  $\geq 4$  log reduction of 2 selected gram positive bacteria, 2 selected gram negative bacteria, and two selected fungus/yeast micro-organisms for a period of time from 3 minutes. The Efficacy testing methods and organisms are the same as those tested for the Curoos Predicate device which was cleared under 510(k) K111992.

The Curoos Red device has been tested to meet the requirements of ISO 594-2 testing for sections: ease of assembly, rotational force to remove (un-torque evaluation) and leakage using water under pressure and leakage using vacuum with air. The testing was completed in accordance with Ivera test protocols. Ivera also completed Simulated Clinical Condition Evaluation testing to demonstrate that the Subject device seals and acts as a cover for the port.

The efficacy test results are summarized in Table 1.

Table 1 - Efficacy Test Results

<b>Organism</b>	<b>Acceptance Criteria (bacterial count reduction (<math>\Delta</math>Log))</b>	<b>3 minute exposure (bacterial count reduction (<math>\Delta</math>Log))</b>
<b>Staphylococcus aureus</b>	<b><math>\geq 4</math> Log</b>	<b>6.7 Log</b>
<b>Staphylococcus epidermis</b>	<b><math>\geq 4</math> Log</b>	<b>6.9 Log</b>
<b>Escherichia coli</b>	<b><math>\geq 4</math> Log</b>	<b>6.7 Log</b>
<b>Pseudomonas aeruginosa</b>	<b><math>\geq 4</math> Log</b>	<b>6.9 Log</b>
<b>Candida Albicans</b>	<b><math>\geq 4</math> Log</b>	<b>6.5 Log</b>
<b>Candida Glabrata</b>	<b><math>\geq 4</math> Log</b>	<b>6.8 Log</b>

The Ivera Curos Red is sterilized using a validated Gamma sterilization process which complies with ISO11137-1:2006/(R) Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose. Recognition number 14-225.

ISO11137-2:2006 Sterilization of health care products – Radiation – Part 1: requirements for development of validation and routine control of sterilization process for medical devices. Recognition number 14-297.

11137-3:2006/(R) 2010 10/04/2010 AAMI ANSI ISO 14-298 - Radiation - Part 3: Guidance on Dosimetric Aspects. Recognition number 14-298. FDA recognized standard ISO11137 Sterilization Standard.

Ivera Medical has completed testing to demonstrate the materials of construction for the Subject Device meet FDA recognized standard ISO10993 for biocompatibility.

**Conclusion**

The analysis arguments and test results demonstrate the Curos Red device is safe for its intended use and is substantially equivalent to the predicate devices.